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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/015,833	12/12/2001	Calvin A. Saravis	TDT-2	7194
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EXAMINER

SAUNDERS, DAVID A

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

015,833

Applicant(s)

SARAVIS et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1-53 is/are pending in the application.
- ☐ Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 1-53 are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-39, drawn to immunogenic compositions comprising a naturally chelating polymer, metal ion, and adjuvant, classified in class 424, subclass 193.1.
- II. Claims 40-42, drawn to immunogenic compositions comprising cross-linked gelatin and an immunogen, classified in class 424, subclass 193.1.
- III. Claims 43-48, drawn to methods of making antibody reagents by immunizing with the immunogens of claims 1 or 37, classified in class 435, subclass 70.21 and class 436, subclasses 547-548.
- IV. Claims 43-48, drawn to methods of making antibody reagents by immunizing with the immunogens of claim 43, classified in class 435, subclass 70.21 and class 436, subclass 547-548.
- V. Claims 49-53, drawn to antibody reagents specific for a metal ion complexed to a naturally-chelating, nonimmunogenic polymer, classified in class 530, subclasses 388.9 and 389.8.

The inventions are distinct, each from the other because:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are different immunogens.

The immunogen composition of Group I requires a naturally chelating nonimmunogenic polymer, while the immunogenic composition of Group II requires

cross-linked gelatin. While certain dependent claims of Group I require presence of cross-linked gelatin (claims 26, 31-32), in such case the gelatin is a component provided in addition to the chelating component of Group I, while the immunogen of Group II is not required to have any chelating function.

Also, the immunogenic composition of claim 1 requires presence of a metal ion, while the immunogenic composition of Group II requires presence of an immunogen, not recited in any claim as a metal ion.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product has other uses. For example, because the metal ion can be chelated reversibly to the nonimmunogenic polymer, the product could be used in a therapeutic method to deliver a metal ion to treat a mineral deficiency.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product has other uses. For example the cross-linked gelatin containing an immunogen could be used to deliver a drug (immunogen) as a sustained-release composition.

Inventions III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by other processes, for example, by using a metal ion or immunogen complexed with an immunogenic polymer. Applicant's disclosure admits (specification pages 5-6) that antibodies specific to a metal ion can be obtained by certain steps taken in screening for hybridomas (to obtain monoclonal antibodies) or in affinity purification (to obtain polyclonal antibodies).

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, or any other Group, restriction for examination purposes as indicated is proper.

Likewise the search for any of Groups II-V does not require a search for any of the other Groups.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1644

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders: jmr

September 17, 2003

*David A. Saunders*  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182/1644